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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/199,129	11/24/1998	JOSEPH R. BYRUM	38-2115075B	3322

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LAWRENCE M. LAVIN
MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
BB4F
ST. LOUIS, MO 63198

EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	14

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/199,129	Applicant(s) BYRUM ET AL.	
	Examiner Karen Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that a search of all of the claims would not constitute a burden to the examiner because a computer search for the nucleic acids of group I could simultaneously search the proteins and methods of Groups II and III. This is not found persuasive because a search for the nucleic acids of Group I would not provide a proper search for the proteins or methods claimed in Group II or III, respectively, and each of these groups would require a different search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 3 and 13-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10. It is noted that Applicant states in the status of claims (see p 5 of Applicant's response filed Nov. 27, 2001) is that claims 2, 3 and 13-17 have been canceled, however, Applicant has not requested the cancellation of any claims and, therefore, claims 1-17 are pending.

This application contains claims 2, 3 and 13-17 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The objection to the specification set forth in the prior Office action (mailed 03-28-01) has been withdrawn in response to Applicant's amendments filed Nov. 27, 2001.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 4-12 are maintained as rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility for the reasons of record set forth in the prior Office action (mailed 03-28-01). This rejection is repeated herein.

Claims 1 and 4-12 are drawn to a nucleic acid comprising a nucleic acid of SEQ ID NO:1. SEQ ID NO:1 is an EST isolated from soybean leaf tissue. Applicant asserts a general utility for this EST (as well as 5520 other EST isolated from the same source) as useful in the isolation of agronomically important genes, as well as generic uses such as antibody production, gene expression probe, marker, etc. The application does not disclose a utility specific for a nucleic acid comprising SEQ ID NO:1 or a specific utility or activity for a protein or fragment encoded by a nucleic acid encoding SEQ ID NO:1, nor does it disclose a specific utility for any full length gene which could be isolated using SEQ ID NO:1.

The claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids (and proteins encoded by said nucleic acids) are not specific and are generally applicable to any nucleic acid and/or protein. The specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. Similarly, protein may be used for detection of expression, antibody production, Western blots, etc. These are non-specific uses that are applicable to nucleic acids and/or proteins in general and not particular or specific to the nucleic acids (and proteins encoded by said nucleic acids) being claimed.

Further, the claimed nucleic acid (and proteins encoded by said nucleic acids) are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have specific

and substantial utilities. The research contemplated by applicants to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds (or proteins encoded by said nucleic acid compounds) such that another non-asserted utility would be well established for the compounds.

Because there is no specific utility for a nucleic acid comprising SEQ ID NO:1 (as discussed above), there is also no specific utility for a plant comprising a nucleic acid comprising SEQ ID NO:1, or its complement, nor is there any specific utility for methods of determining the level or pattern of a protein which has no specific utility using SEQ ID NO:1 or its complement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-12 are also maintained as rejected under 35 U.S.C. § 112, first paragraph for the reasons of record set forth in the prior Office action (mailed 03-28-01). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1 and 4-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 1. SEQ ID NO: 1 meets the written description provisions of 35 USC 112, first paragraph. However, SEQ ID NO:1 is a partial sequence, and the proper open reading frame has not been disclosed. Claims 1 and 4-12 are directed to encompass full length gene sequences (ie. gene sequences yet to be discovered) and cDNAs comprising SEQ ID NO:1, sequences that hybridize to SEQ ID NO: 1, and so forth, as well as plants comprising said sequences and methods which utilize said sequences. None of these sequences meet the written description provision of 35 USC 112, first paragraph. For example, cDNA comprising a partial sequence encompasses a wide variety of subgenera with widely varying attributes. For

example, a cDNA's principle attribute would include its coding region, however, the specification does not disclose an open reading frame for SEQ ID NO:1 and, therefore, would not be representative of the genus of cDNA's because no information regarding the coding capacity of any cDNA molecule would be disclosed. In the instant case, the specification discloses only a single common structural feature shared by the claimed genus, ie. SEQ ID NO:1, and this disclosed structural feature does not constitute a substantial portion of the claimed genus. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes

v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

Applicant's arguments filed November 12, 2001 have been fully considered but they are not persuasive.

In response to the rejection of claims 1 and 4-12 under 35 U.S.C. § 101 on the grounds that the claimed invention lacks patentable utility and the associated rejection of claims 1 and 4-12 under 35 U.S.C. § 112, first paragraph, Applicant argues that the specification provides adequate and substantial utility for the claimed oligonucleotides.

Applicant is directed to the Utility Examination Guidelines, Federal Register Vol. 66, No. 4, Pages 1092-1099, January 5, 2001.

As set forth in the prior Office action (mailed 03-28-01) the specification discloses no specific and substantial for the claimed polynucleotides. The various asserted utilities for the claimed polynucleotides are not specific, as these asserted utilities can be ascribed to any polynucleotide, and not just to the particular claimed polynucleotides. This utility is not substantial, as it would require more research to identify particular properties and usefulness of the polynucleotides and/or related gene. Basic research such as studying the properties of the claimed product itself or the mechanism in which the material is involved is not a substantial utility. There is insufficient support in the specification to indicate that the present invention as claimed meets the criteria of a specific and substantial and credible utility or, in the alternative, a well established utility. Applicant has not identified a specific utility, thus the claimed invention is not presumed to possess it. *In re Cortright*, 165 F.3d 1353, 1357, 49 USPQ2d 1464; *In re Brana*, 51 F.3d 1560, 1566; 34 USPQ2d 1436 (Fed. Cir. 1995).

Applicant asserts that the rejection made under 35 U.S.C. 101 ignores utilities disclosed in the specification, and contravenes prevailing law. Applicant cites several decisions, including *Raytheon Co v. Roper Corp*. 724F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983); and *Carl Zeiss Stiftung v. Reinshaw PLC*, 945 F2d 1173, 1180, 20 U.S.P.Q.2d 1094 1100 (Fed. Cir. 1991) in support of their assertion that the Guidelines contravene prevailing law, however, these decisions are distinguishable from this application on their facts, and Applicant is reminded of

Brenner v. Manson, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689 (1966) which stated that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As set forth above, the myriad of asserted utilities are general utilities applicable to a broad class of compounds, and do not meet the specific, substantial and credible criteria for utility under the present guidelines. The additional potential utilities suggested by Applicant (identifying and generating mutations, investigating links, identifying and isolating related molecules, etc.) are an invitation to do further research to search for a specific and substantial utility for the claimed polynucleotides. Further, no readily apparent well-established utility for any one polynucleotide is set forth in the specification.

Applicant further argues that under the published Utility Examination Guidelines, certain other types of inventions would not be patentable, such as microscopes and golf clubs, however, the utility of those apparati are not sufficiently related to the isolated polynucleotides under examination such that any definite conclusions as to utility can be drawn. Applicant notes "An important utility of a microscope resides in its use to identify...", however, whether that utility is the only utility or the only patentable utility of those inventions is not clear, and not at issue here.

Applicant asserts that each isolated polynucleotide will identify "a unique subset of related sequences" but fails to set forth exactly what those sequences are for the claimed polynucleotides. Further, there is the question of how to use the resulting unique subset of related sequences, i.e. what is their substantial and specific utility.

Applicant argues that the failure to assess whether the asserted utilities are credible renders the rejection incomplete and improper. This argument does not address the lack of substantial and specific utility, and is therefore not persuasive. The specification does not set forth a specific and substantial utility for the claimed polynucleotides. In the absence of any evidence of record, e.g. test data, affidavits or declarations from Applicant, the inventor(s) or experts that are probative of Applicant's assertions, this rejection will be maintained.

In response to the rejection of claims 1 and 4-12 under 35 U.S.C. §112, first paragraph as lacking an adequate written description Applicant argues that Applicant is not required to describe all things that are encompassed by the claims and that Applicant need not describe every aspect of the claimed nucleic acid molecules, including the open reading frame. Applicant argues that nucleic acids falling within the scope of the claimed invention are readily identifiable in that they comprise SEQ ID NO:1 and complements thereof. Applicants argue that modifications to the claimed polynucleotides can readily be envisioned by one of ordinary skill in the art from the instant specification.

Applicant is directed to the Written Description Examination Guidelines, Federal Register Vol. 66, No. 4, Pages 1099-1107, January 5, 2001.

The specification discloses only a single structural feature shared by members of the claimed genus, i.e., SEQ ID NO:1. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus.

In the instant case, claims 1 and 4-12 encompass full-length genes and cDNAs which are not described by the one disclosed species because SEQ ID NO:1 is only a fragment of any full-length gene or cDNA and there is substantial variability among the species of DNA encompassed within the scope of the claims. Although Applicant need not describe every feature of a claimed invention, there must be adequate disclosure of the necessary common attributes and features of the claimed genus. For example, a cDNA's principle attribute would include its coding region. The partial cDNA disclosed in the specification (SEQ ID NO:1) does not include a disclosure of any open reading frame of which it would be a part. SEQ ID NO:1 is not representative of the genus of cDNA's encompassed in the claims because no information regarding the coding capacity of any cDNA molecule was disclosed. The claimed genus encompasses genes yet to be discovered and the one disclosed structural feature (SEQ ID NO:1) does not constitute a substantial portion of the claimed genus. One skilled in the art would not be able to envision the structural features of the genus claimed based on the one disclosed structural feature, SEQ ID NO:1.

Conclusion

Any rejection of record not repeated herein is considered to be withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523. The examiner can normally be reached Monday-Thursday 8:30 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
January 30, 2002

ANDREW WANG
PRIMARY EXAMINER